IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9178

Bartle, J. December 10, 2013

Hale R. Harding ("Mr. Harding" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. JoAnn D. Harding, Mr. Harding's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2011, claimant submitted a completed supplemental Green Form to the Trust signed by his attesting physician, Leon J. Frazin, M.D., F.A.C.C. Based on an echocardiogram dated October 29, 2002, Dr. Frazin attested in Part II of Mr. Harding's Green Form that claimant suffered from severe mitral regurgitation, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction of less than 30%, and ventricular fibrillation or sustained ventricular tachycardia which resulted in

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

hemodynamic compromise.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits[5] in the amount of $1,102,453.[6]

In the report of claimant's October 29, 2002 echocardiogram, the reviewing cardiologist, Mark Eaton, M.D., observed that Mr. Harding had mitral annular calcification.[7] Dr. Frazin, however, attested in claimant's Green Form that Mr. Harding did not suffer from mitral annular calcification. In

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4. Dr. Frazin also attested that claimant suffered from New York Heart Association Functional Class III symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant qualifies for Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.c.(2)(b). The Trust did not contest that Mr. Harding's October 29, 2002 echocardiogram demonstrated that claimant suffered from one of the complicating factors necessary to qualify for a Level II claim and that claimant had ventricular fibrillation.

6. Mr. Harding previously was paid Matrix B-1, Level II benefits in connection with a Green Form completed by Waenard Miller, M.D., based on an echocardiogram dated January 14, 2002. Claimant, therefore, is entitled, if at all, only to the difference between the Matrix B-1, Level II benefits already paid and the amount of benefits associated with the Matrix and Level for which he establishes a reasonable medical basis. See Settlement Agreement § IV.C.3.

7. In addition, Dr. Miller attested in connection with claimant's earlier Green Form that Mr. Harding had mitral annular calcification.

addition, in February, 2012, Dr. Frazin submitted a declaration wherein he stated, in relevant part, that:

> 2. I reviewed again the Hale Harding echocardiogram dated 10/29/02 at the request of the AHP Settlement Trust.
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> 3. Regarding question D9: The reason why mitral annular calcification (MAC) is not present on that echocardiogram is that the echo reflectivity of the mitral annulus is the same as that of the inferior basilar and lateral basilar myocardial walls.

Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

Dr. Eaton also observed, in the report of claimant's October 29, 2002 echocardiogram, that Mr. Harding had "[m]oderate mitral regurgitation." Dr. Eaton, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In March, 2012, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for Dr. Frazin's finding that claimant had severe mitral regurgitation because claimant's

October 29, 2002 echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Wang stated, "The RJA/LA area ratio was less than 20%. The RJA encircled should not include the area of low velocity flow." In addition, Dr. Wang concluded that there was no reasonable medical basis for Dr. Frazin's finding that claimant did not have mitral annular calcification. On the contrary, Dr. Wang stated, "There was evidence of mitral annular calcification."

Based on Dr. Wang's findings, the Trust issued a post-audit determination denying Mr. Harding's claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant argued that the auditing cardiologist erred in failing to find a reasonable medical basis for at least moderate mitral regurgitation based on claimant's October 29, 2002 echocardiogram. In support, claimant submitted a declaration from Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A., wherein he explained that "the 10/29/02 study showed at least moderate [mitral regurgitation]."[9]

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Harding's claim.

9. Claimant also submitted reports for echocardiograms of February 8, 2001 and October 16, 2003. Claimant also submitted

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Claimant also argued that the auditing cardiologist erred in failing to find a reasonable medical basis for the absence of mitral annular calcification on or before the end of the Screening Period. According to Mr. Harding, his claim should not be reduced to Matrix B-1 because the Settlement Agreement requires that the presence of a reduction factor such as mitral annular calcification must be diagnosed between the commencement of Diet Drug use and the end of the Screening Period. In any event, claimant says, "Only Dr. Leon Frazin and Dr. Paul Dlabal carefully considered the question about whether or not the calcification found on the mitral valve leaflets actually extended to the annulus." In support, claimant again relied on Dr. Dlabal's declaration wherein he stated, in relevant part, that:

> 10. [T]he 1/14/02 study and the 10/29/02 study did not show mitral annular calcification (MAC). Both of these echocardiograms showed calcification of the posterior leaflet of the mitral valve (PLMV), which is not the same as MAC. On both of these studies, the calcification did not extend to the annulus. As validation, the calcium moved with the mitral valve, but not with the annulus.

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9. (...continued)
an affidavit from a records custodian, which stated that the actual echocardiogram tapes could not be located. The report of claimant's February 8, 2001 echocardiogram stated that "2-3+ mitral insufficiency is detected by color-flow Doppler." The report of claimant's October 16, 2003 echocardiogram stated that "2+ mitral insufficiency is detected by color-flow Doppler." The report further recorded: "Mitral annular calcification is demonstrated."

> 11. Moreover, Dr. Leon J. Frazin stated that MAC was not present on the 10/29/02 study, because the density of the mitral valve annulus was equivalent to that of the surrounding myocardial walls. I concur with this statement.
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> 12. Further, on the apical four-chamber view, the apparent calcification of the mitral valve annulus was once again artifact.
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> 13. In this case, the calcification of the posterior leaflet of the mitral valve was not due to MAC. On the occasions when valvular calcification secondary to MAC does occur, the MAC is very pronounced, the MAC precedes the development of the leaflet calcification, and the MAC is substantially greater in thickness than the calcification involving the leaflets. No such conditions occurred in this case.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang submitted a declaration in which she confirmed her previous conclusions that there was no reasonable medical basis for finding that claimant had moderate mitral regurgitation on the October, 29, 2002 echocardiogram and no reasonable medical basis for finding that claimant did not have mitral annular calcification. Specifically, Dr. Wang stated, in pertinent part, that:

> 10. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had severe mitral regurgitation. At Contest, I again observed that Claimant's October 29, 2002 echocardiogram of attestation demonstrated only mild mitral regurgitation. There is no reasonable medical basis to conclude that even

moderate mitral regurgitation is present in this study.

11. I also confirm my finding at audit, that there is no reasonable medical basis for the representation that Claimant did not have mitral annular calcification. Mitral annular calcification was seen in the parasternal view, short axis view (5 o'clock at mitral valve level) and 4 chamber view on the October 29, 2002 study, and on all of the other studies I reviewed. Claimant clearly had mitral annular calcification, and there is no reasonable medical basis to conclude otherwise.

12. At Contest, in addition to the October 29, 2002 echocardiogram of attestation, I reviewed studies dated 1/14/02, 12/17/04, 10/3/07, 12/6/10, and 7/7/11. Mitral regurgitation was mild in all studies. The mitral regurgitation jet area was traced on the 1/14/02 study, and the RJA encircled clearly included low velocity flow. There is no reasonable medical basis to conclude that moderate mitral regurgitation is present on any of these studies. In addition, mitral annular calcification may be seen on all of these studies in the parasternal view, short axis view (5 o'clock at mitral valve level) and 4 chamber view, as noted above. There is no reasonable medical basis to conclude that mitral annular calcification was not present.

13. I also considered Dr. Dlabal's statement that Claimant did not have mitral annular calcification, because the calcification seen on Claimant's studies' [sic] moved with the mitral valve[]. Mitral annular calcification is calcium deposited along and beneath the mitral valve annulus. MAC generally follows the c-shape of the mitral annulus so the base of the anterior mitral leaflet is generally (but not always) spared. When MAC is very severe, it can extend to the posterior

> mitral valve leaflet, but not the other way around. In this case, there is a small bright echodensity located at the mitral annulus (at the base of or beneath the posterior leaflet) which is best seen at the parasternal long axis and short axis (5 o'clock at the mitral valve level.) Since the posterior mitral valve leaflet is attached to the posterior annulus, the MAC moves with the valve and annulus. There is no reasonable medical basis to conclude that mitral annular calcification was not present.

The Trust then issued a final post-audit determination, again denying Mr. Harding's claim. Claimant disputed this final determination and requested that his claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Harding's claim should be paid. On November 8, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8959 (Nov. 8, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 14, 2003, and claimant submitted a sur-reply on March 6, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a

Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Mr. Harding has met his burden of proving that there is a reasonable medical basis for finding that he suffered from moderate mitral regurgitation on the October 29, 2002 echocardiogram and that he did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Harding reasserts the arguments he raised in contest. In addition, claimant submitted a supplemental declaration of Dr. Dlabal wherein he stated, in pertinent part, that:

> 11. In this case, calcium was not deposited along and beneath the mitral valve annulus on the 2002 studies, and [mitral annular calcification] did not follow the c-shape of the mitral annulus.
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> 12. More specifically, [mitral annular calcification] was not seen in the parasternal view, short axis view (5 o'clock at mitral valve level) and 4 chamber view, or any other view found on the 10/29/02 study.
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> 13. In his [sic] declaration, Dr. Wang also claimed that severe [mitral annular calcification] can extend to the posterior mitral valve leaflet, but not the other way around. This claim is false. Calcification may originate on the posterior mitral valve leaflet without having an effect on the annulus. That is exactly what happened in this case.
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> 14. Dr. Wang also claimed that "there is a small bright echodensity located at the mitral annulus (at the base of or beneath the posterior leaflet) which is best seen at the parasternal long axis and short axis (5 o'clock at the mitral valve level)." This "small bright echodensity" could not represent severe [mitral annular calcification] that extended to the posterior leaflet, as claimed by Dr. Wang. I reviewed all of the views on the 2002 studies listed by Dr. Wang. In the parasternal long axis and short axis (5 o'clock at the mitral valve area) views and 4 chamber view, the small bright spot or apparent (to Dr. Wang) calcification of the mitral valve annulus was artifact.

> 15. Further, although the posterior mitral valve leaflet is attached to the posterior annulus, as I stated in my declaration, the true areas of calcification moved only with the posterior leaflets and these areas did not move with the annulus. Therefore, the true areas of calcification were not located on the annulus.

In response, the Trust reasserts that Mr. Harding has not established a reasonable medical basis for finding that there was moderate mitral regurgitation to support an underlying Level II claim or that he did not have mitral annular calcification. The Trust also contends that Dr. Dlabal's supplemental declaration does nothing to militate against Dr. Wang's findings. Finally, the Trust points out that we previously have rejected the argument that the Trust may not rely on echocardiograms conducted after the Screening Period to find the presence of a reduction factor.

The Technical Advisor, Dr. Vigilante, reviewed claimant's October 29, 2002 echocardiogram and concluded that there was a reasonable medical basis for finding that Mr. Harding's October 29, 2002 echocardiogram demonstrated moderate mitral regurgitation. Specifically, Dr. Vigilante observed that "in the apical two chamber view, the largest representative RJA/LAA ratio [is] 21% consistent with moderate mitral regurgitation."[11] Dr. Vigilante also determined, however, that there was no reasonable medical basis for the attesting

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11. Dr. Vigilante also found that claimant's October 3, 2007 and July 7, 2011 echocardiograms demonstrated moderate mitral regurgitation.

physician's finding that claimant did not have mitral annular calcification. Dr. Vigilante found, in pertinent part, that:

> [A]ll of the reviewed echocardiograms demonstrated obvious and classic mitral annular calcification. An echocardiographer could not reasonably conclude that mitral annular calcification was not present on all six reviewed echocardiographic studies even taking into account the issue of inter-reader variability.

In response to the Technical Advisor Report, claimant asserts that Dr. Vigilante's finding of moderate mitral regurgitation establishes that claimant qualified for Level II Matrix Benefits and, as such, is entitled to receive Level V benefits for his ventricular fibrillation. Claimant also asserted that the Court should disregard Dr. Vigilante's findings as to the presence of mitral annular calcification on echocardiograms performed after the end of the Screening Period because "[t]hese issues are matters of law."

After reviewing the entire Show Cause Record, we find that Mr. Harding has established a reasonable medical basis for finding that his October 29, 2002 echocardiogram demonstrates moderate mitral regurgitation. Although Dr. Wang concluded that claimant's October 29, 2002 echocardiogram demonstrated only mild mitral regurgitation, Mr. Harding's expert, Dr. Dlabal reviewed the echocardiogram and determined that it demonstrated at least moderate mitral regurgitation. In addition, the Technical Advisor reviewed claimant's October 29, 2002 echocardiogram and concluded that it demonstrated moderate mitral regurgitation with

an RJA/LAA ratio of 21%.[12] Thus, claimant has established a reasonable medical basis for finding that he suffered from moderate mitral regurgitation based on his October 29, 2002 echocardiogram.

As noted, a claimant is entitled to Level V benefits if he or she qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). Mr. Harding qualifies for Level II benefits based on his October 29, 2002 echocardiogram and he subsequently suffered an episode of ventricular fibrillation in September, 2010. Accordingly, he has satisfied the criteria for Level V benefits. See, e.g., Mem. in Supp. of PTO No. 9132, at 10-11 (Aug. 16, 2013).

We must, however, still determine whether claimant should be paid on Matrix A-1 or Matrix B-1. As noted previously, the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)d). Although claimant contends, through his expert, Dr. Dlabal, that his October 29, 2002 echocardiogram is not demonstrative of calcification extending to the annulus, the auditing cardiologist and the Technical Advisor each reviewed claimant's echocardiograms and concluded that there was no reasonable

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12. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

medical basis for Dr. Frazin's representation that Mr. Harding did not have mitral annular calcification. In particular, Dr. Wang stated that "[c]laimant clearly had mitral annular calcification" based on his October 29, 2002 echocardiogram and that mitral annular calcification was seen "on all of the other studies I reviewed."[13] Similarly, Dr. Vigilante concluded that claimant's echocardiograms of January 14, 2002; October 29, 2002; December 17, 2004; and October 3, 2007 "demonstrated obvious and classic mitral annular calcification." Further, the overwhelming majority of the reports for claimant's echocardiogram state that Mr. Harding had mitral annular calcification.[14] Moreover, in claimant's earlier Green Form, Mr. Harding's attesting physician, Dr. Miller, represented that claimant did have mitral annular calcification (based on a January 14, 2002 echocardiogram).

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13. Dr. Wang also noted that the calcification on the posterior leaflet of Mr. Harding's mitral valve, a condition conceded by Dr. Dlabal, was evidence of mitral annular calcification because "[w]hen [mitral annular calcification] is very severe, it can extend to the posterior mitral valve leaflet, but not the other way around." Although Dr. Dlabal disagreed in his supplemental declaration with Dr. Wang's statement, he did not submit any medical evidence to support his assertion. Mere disagreement with the Technical Advisor is insufficient to meet a claimant's burden of proof.

14. In the Technical Findings Report for Mr. Harding's January 14, 2002 echocardiogram, the reviewing cardiologist indicated "Y" as to whether claimant had "MAC." The report for claimant's December 17, 2004 echocardiogram states that "[t]he mitral valve has annular calcification." Similarly, the report for claimant's October 3, 2007 echocardiogram states that "[t]he mitral annulus is calcified." Finally, the reports for claimant's December 6, 2010 echocardiogram and July 7, 2011 echocardiogram both state that there is "[m]ild mitral annular calcification present."

Thus, we find that claimant has not met his burden of proving that there is a reasonable medical basis for Dr. Frazin's representation that claimant did not suffer from mitral annular calcification based on his October 29, 2002 echocardiogram.

In any event, none of claimant's physicians ever disputed that Mr. Harding's December 17, 2004 and October 3, 2007 echocardiograms demonstrate the presence of mitral annular calcification.[15] Instead, claimant only argues that these later echocardiograms should be disregarded because, according to claimant, the reduction factors set forth in the Settlement Agreement, such as mitral annular calcification, have a temporal limitation. We recently rejected this argument, holding that "[t]o avoid receiving reduced Matrix Benefits, claimant must demonstrate, at a minimum, that she did not suffer from a reduction factor at the time she suffered from the conditions supporting her supplemental claim." See Mem. in Supp. of PTO No. 8822, at 9 (Feb. 22, 2012), aff'd, In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 525 F. App'x 140 (3d Cir. 2013); see also Mem. in Supp. of PTO No. 8743, at 2-7 (Dec. 27, 2011). As claimant does not dispute the presence of mitral annular calcification prior to his September, 2010 episode of ventricular fibrillation, the

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15. Indeed, although Dr. Frazin and Dr. Dlabal submitted declarations on behalf of claimant, each opined only that mitral annular calcification was not present on claimant's January 14, 2002 and October 29, 2002 echocardiograms.

Settlement Agreement requires that his Level V claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has met his burden of proving that there is a reasonable medical basis for his claim for Matrix B-1, Level V benefits only. Therefore, we will affirm the Trust's denial of the claims of Mr. Harding and his spouse for Matrix A, Level V benefits, but will reverse the Trust's denial of the claims of Mr. Harding and his spouse for Matrix B, Level V benefits.